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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,444	02/11/2004	Vinayak D. Bhat	03764.P001D	4802

7590

07/10/2006

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EXAMINER

AZPURU, CARLOS A

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 07/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/777,444	Applicant(s) BHAT, VINAYAK D.	
	Examiner Carlos A. Azpuru	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-32 and 48-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27,31,32 and 48-50 is/are rejected.
- 7) ☒ Claim(s) 28-30 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of the amendment filed 04/25/2006.

The rejection under 35 USC 112, first paragraph for scope of enablement is hereby withdrawn.

The following rejection is maintained in this action:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 27, 31, 32, 48, 49, and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Scott et al.

Scott et al disclose a sustained release composition which includes a macromolecule and complexing agents or binding member (see col. 5, lines 25-34). The complexing agent is capable of ionic interaction with the with a therapeutic agent (see col. 5, lines 55-56). Ionic and anionic complexing agents are described at col. 5, lines 61-67. Protein like compounds such as poly-l-lysine may serve as carriers as show at col. 15, lines 48-67; col. 16, lines 1-27. The drug delivery system inherently "hinders

transport of an agent away from tissue and allows the agent to migrate towards the tissue” since a drug delivery system operates by osmotically or actively pumping active agent towards tissue to a higher degree than the active agent would move away from the tissue.. Administration to myocardial tissue is disclosed at col. 11, line 28 (catheterization or angioplasty). The delivery carrier is dependent upon the tissue to which the delivery system is administered, but in the case of myocardial delivery, a catheter is clearly indicated by the reference. The instant claims are anticipated by Scott et al.

Response to Arguments

Applicant's arguments filed 04/252/006 have been fully considered but they are not persuasive.

Applicant argues that Scott et al lacks a teaching of a “binding member having sufficient property adapted to couple to a surface of the tissue”. While applicant's arguments concerning the complexing agents are correct, it must be pointed out that Scott et al does indeed include a binding agent at col. 14, lines 61-67; col. 15, lines 1-11. In this section Scott et al disclose cleavable molecules which are attached to the microspheres (barrier) which are designed to target a predetermined site under appropriate biological conditions. Exposure to a change in these conditions (such as pH change) would then cause cleavage, and release of the bioactive. A pKa range of between 6 and 10 would be inherent to any biologically administered system, since the

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capacity to buffer beyond this range would be dangerous to physiological systems. The microspheres (barrier) are attached to or taken up by the cells. A diester bond is cited as an example of a cleavable bond. This covalent binding would by definition include sharing of electrons. As such, the instant claims are anticipated by Scott et al.

The following is a rejection of the newly presented claims :

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 49 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a cationic or anionic binding member, does not reasonably provide enablement for all binding members. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant clearly sets out that when binding is ionic, there is a strong advantage to using barriers which are ionically charged at or near neutral pH. This includes pH of between 6-10. Thus anionic or cationic binding members having a pKa of between 6 and 10 (see page 15, lines 23-26). Appropriate correction is requested.

Claims 28-30 are objected to as dependent upon a rejected base claim.

The Handbook of Refractory Carbides and Nitrides is cited for its definition of a covalent bond.

Conclusion

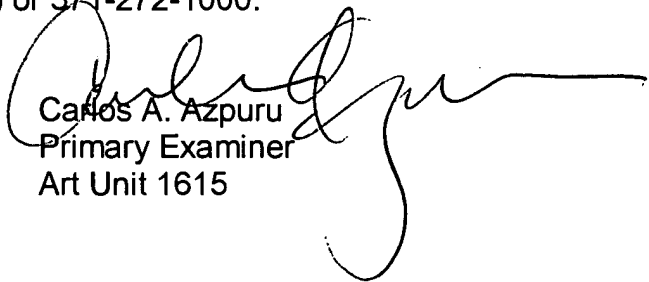
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Carlos A. Azpuru
Primary Examiner
Art Unit 1615

ca